

CONSENT FOR RESEARCH
Penn State College of Medicine
The Milton S. Hershey Medical Center

Title of Project: Exercise in Radiation Therapy (EXERT)

Principal Investigator: Nicholas G Zaorsky, MD

Address:

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Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. 717-531-8024
After hours call (717) 531-8521. Ask for the Radiation Oncology doctor on 24-hour call.

Subject's Printed Name: _____

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

1. Why is this research study being done?

You are being asked to participate in this research study because you are patient at Penn State Milton S. Hershey Medical Center and are undergoing radiation therapy for cancer.

The primary purpose of this study is to determine if patients are accepting of, and will participate in, one-on-one counseling for exercising throughout your cancer treatment. While avoiding physical inactivity is recommended, we seek to understand if our counseling will help you become more active and that we do it in a safe way.

Another purpose of this study is to evaluate if patients receiving one-on-one counseling for exercise have fewer side effects from their radiation therapy and better physical function after completing the radiation therapy.

Approximately 50 people will take part in this research study at the Hershey Medical Center.

2. What will happen in this research study?

- At the time of initial consultation with your radiation oncologist, we will tell you about the research study. You will continue to receive your radiation therapy, as per the standard of care. Additionally, we will ask you to participate in exercise therapy sessions, starting soon after your consultation.

You will allow us to collect information from your electronic medical record related to your cancer diagnosis such as diagnosis, date of diagnosis, and medical history.

- The exercise counseling sessions will take 20-40 minutes (before your radiation therapy) depending on the topic and your questions. What will happen at these counseling sessions:
 - Surveys will be done at every exercise counseling sessions.
Surveys include questions on your: physical activity, ability to exercise, common diet, quality of life and side effects to cancer treatment.
- Meet weekly with a cancer exercise physiologist before radiation therapy for exercise counseling.
 - Exercise counseling means meeting with the cancer exercise physiologist one-on-one to learn about topics like: special considerations for exercise specific to your cancer and your treatment, different modes of physical activity that are possible and what intensities to do the exercise at, what different intensities of exercise should feel like, making sure you do proper warm ups and cool downs, showing you proper stretching techniques, learning how to use equipment properly for safe exercise.
- The physical functioning testing will take about 30 minutes to explain the instructions and complete the tasks. These tests will be done at the first and last exercise counseling session. Surveys will also be completed at these visits. Surveys will have to do with your physical activity, ability to exercise, common diet, quality of life and side effects to cancer treatment as well as an injury history questionnaire.
- The physician functioning testing involves the following:
 - Strength is measured by gripping and squeezing a small device with your hand that measures how hard you squeeze.
 - Endurance is measured by 1) seeing how many times you can stand up/sit down in a chair over 30 seconds; and 2) seeing how quickly you can stand up from a chair, walk a few feet away, and return to sitting in the chair.
 - Balance is measured by asking you to stand for ten seconds with your feet in various different positions (4 stances).
- You will also be provided an exercise prescription to follow at home, in between radiation therapy, and you will be asked to record what you do between visits. The cancer exercise specialist will then review these records and provide guidance. These exercises will be specifically tailored for you.
 - You will continue to perform exercise therapy at home once per day, between 1 to 7 times per week (as you can tolerate it), about 1 hour per session.
 - You should continue to perform exercise therapy as tolerated during the follow up period.

What are my responsibilities if I take part in this research?

If you take part in this research, your major responsibilities will include:

- coming to the scheduled appointments for exercise counseling (which will always occur on the same day as a radiation therapy visit)
- completing the physical function testing and surveys
- recording your exercise activities between visits

3. What are the risks and possible discomforts from being in this research study?

Risks of Loss of Confidentiality

There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

Risks of exercise training.

There are a few risks involved in attending the exercise sessions. The risk of an exercise training induced cardiac (heart) event is about 1 event per 1.7 million walk/jogging miles. You may experience some mild muscle soreness at the beginning of your activity program. Other risks or discomforts may include changes in the strength or sensations in your arms or legs, muscle or ligament strain, or a temporary increase in back pain. These changes are rarely serious. Less common risks associated with physical activity include changes in blood pressure or heart rhythm, dizziness, or fainting. Other risks of exercise are: fracture (such as spine compression fracture), shortness of breath, undue fatigue, chest pain, low blood glucose levels, heart attack. However, even in individuals with known heart disease, the risk of a heart attack with aerobic exercise is less than 1 in 10,000; and this protocol does not include aerobic exercise. Study staff will monitor all of your sessions to reduce these risks. We also ask you to call us if any of your symptoms become severe.

Risks for surveys

There are no medical risks associated with filling out surveys, however one may become uncomfortable providing personal information. Any questions that make you uncomfortable can be skipped.

Risks for physical functioning testing

Performance of the chair stands, timed up and go, and balance tests can result in muscle injury or falls. This risk will be minimized by having trained staff perform the tests and monitor participants closely. If it becomes apparent that the activity cannot be continued without injury, the staff will stop the evaluation activity.

If any important new information about the study develops that may affect your health, welfare, or willingness to stay on the study, your study doctor will tell you. You may be asked to sign another consent form at that time.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to me?

There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include decreasing your risk for chronic diseases and cancer related fatigue, improving your quality of life, and completing radiation therapy with better function than if you do not exercise.

4b. What are the possible benefits to others?

The information obtained from this research study may benefit future cancer patients by demonstrating safety and utility of exercise counseling in cancer care.

5. What other options are available instead of being in this research study?

You may choose not to be in this research study. Another option is self-directed exercise.

You do not have to take part in this study to be treated for your condition. Instead of participating in this research, you could:

- Be part of a different research study, if one is available.
- Choose to follow a self-directed exercise program.

Before you decide if you want to be in this research, we will discuss the other choices that are available to you. We will tell you about the possible benefits and risks of these choices.

6. How long will I take part in this research study?

If you agree to take part, you will receive exercise counseling for the duration of your radiation therapy (approximately 3-8 weeks, depending on your radiation therapy schedule and length).

We also may review your medical record information for up to 12 months following completion of the study.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information. In our research files at The Milton S. Hershey Medical Center (HMC) and Penn State College of Medicine (PSU) we will include these identifiers your name, address, phone number, email address, date of birth, medical record number, a code number

- A list that matches your name with your subject ID number will be kept in a locked file in Dr. Zaorsky's office.
- Your research records will be labeled with subject ID number and will be kept in a safe area in Dr. Zaorsky's research office.
- A copy of this signed consent form will be included in your HMC medical record. This means that other HMC healthcare providers will know you are in this study.
- We may use your research information in future studies or may share your information with other investigators for future research without your additional informed consent. Before we use or share your information we will remove any information that shows your identity.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

7b. How will my identifiable health information be used?

If you give your consent, health information that can be traced to you will be collected for this research study. In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so. We will use and disclose your information only as described in this form and in the HMC Privacy Notice.

The research team may use the following health information:

- Past, present, and future medical records

- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The following people/groups may see, use, and share your identifiable health information:

- HMC/PSU research staff involved in this study
- The HMC/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The HMC/PSU Human Subjects Protection Office
- The HMC/PSU Research Quality Assurance Office
- Non-research staff within HMC/PSU who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Organizations that provide independent accreditation and oversight of hospitals and research
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

These groups may also review and/or copy your original PSU/HMC records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

Because research is an ongoing process, your permission for the use, storage and sharing of your health information will continue indefinitely.

Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to take part in this research study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the front of this form. Once permission is withdrawn, you cannot continue to take part in the study.
- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and we will not be able to take back information that has already been used or shared with others.
- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?

For costs of tests and procedures that are only being done for the research study:

- The exercise counseling will be provided by the research at no cost to you.
- You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your condition.
- The research-related tests and procedures that will be provided at no cost to you include: research-related surveys and physical function testing (strength, endurance, and balance).

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

8b. What happens if I am injured as a result of taking part in this research study?

It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility. If you experience a side effect or injury and you believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal investigator will arrange for medical treatment.

HMC/PSU compensation for injury

- There are no plans for HMC/PSU to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.
- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

When you sign this form you are not giving up any legal right to seek compensation for injury.

9. Will I be paid to take part in this research study?

You will not receive any payment or compensation for being in this research study.

10. Who is paying for this research study?

The institution and investigators are not receiving any funds to support this research study.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?

Please call the head of the research study (principal investigator), Nicholas Zaorsky at 717-531-8024, or the Penn State Hershey Medical Center operator at 717-531-8521 and ask for the Radiation Oncology doctor on 24-hour call if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the research protection advocate in the HMC Human Subjects Protection Office (HSPO) at 717-531-5687 if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

You may visit the Penn State College of Medicine's Clinical Research web site at <http://med.psu.edu/clinical-research/faqs> for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the HSPO at (717) 531-5687.

INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name
(Only approved investigators for this research may explain the research and obtain informed consent.)			

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and agree to allow your information to be used and shared as described above.

Signature of Subject

Date

Time

Printed Name